IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MICHAEL R. HRICIK	:	CIVIL ACTION
	:	
v.	:	No. 14-3228
	:	
STRYKER BIOTECH, LLC, et al.	:	

MEMORANDUM

Juan R. Sánchez, J. **January 30, 2015**

Plaintiff Michael R. Hricik brings claims against Stryker Biotech, LLC, Howmedica Osteonics Corporation, and Stryker Corporation (collectively, "Stryker"), and two individual Stryker sales representatives, Michael Cowgill and Kevin O'Dare, arising out of Defendants' allegedly illegal promotion of an off-label[1] use of OP-1 Implant and Calstrux, two medical devices manufactured and marketed by Stryker. Hricik underwent spinal fusion surgery in which his surgeon used OP-1 Implant and Calstrux in the off-label manner promoted by Defendants and sustained serious and permanent injuries as a result. He seeks to hold Stryker and the sales representatives who promoted the off-label use to his surgeon liable for his injuries under a variety of legal theories.

After Hricik filed suit in state court, Stryker removed the case to this Court, asserting the case is within the district courts' original jurisdiction under the diversity statute, 28 U.S.C. § 1332. Although Hricik, Cowgill, and O'Dare are all alleged to be citizens of Pennsylvania, Stryker argues the requirement of complete diversity is nevertheless satisfied because Cowgill

[1] A prescription drug or medical device is used off-label when it is used for a purpose other than the purpose for which it has been approved by the Food and Drug Administration (FDA). *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 350 (2001). Although physicians may lawfully prescribe drugs or use medical devices in an off-label manner, the Federal Food, Drug and Cosmetic Act "generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs [or devices] for such unapproved . . . uses." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2012).

and O'Dare were fraudulently joined and their citizenship should therefore be disregarded for jurisdictional purposes. Hricik disputes that Cowgill and O'Dare were fraudulently joined and asks this Court to remand the case to the Court of Common Pleas of Philadelphia County. Because Stryker has not met its "heavy burden" to persuade the Court that there is "no reasonable basis in fact or colorable ground supporting" any of Hricik's claims against Cowgill and O'Dare, *Boyer v. Snap-on Tools Corp.*, 913 F.2d 108, 111 (3d Cir. 1990) (citations omitted), Hricik's motion to remand will be granted.

FACTS[2]

OP-1 Implant is a Bone Morphogenic Protein (BMP) with the ability to stimulate, repair, and regenerate bone. In 2001, OP-1 Implant received limited FDA approval for use in patients with long bone fractures that failed to heal with other treatment and for whom autograft (i.e., bone harvested from the patient him or herself) was not feasible. A companion Stryker OP-1 product—OP-1 Putty—received limited FDA approval in 2004 for use in patients needing spinal fusion surgery after a prior spinal surgery had failed and for whom autograft was not feasible.

After receiving complaints from surgeons that the OP-1 products had "poor handling" and "insufficient volume," Stryker developed Calstrux for use as a "carrier" or "extender" with the OP-1 products to address these handling and volume issues. *See* Compl. ¶¶ 33-36. Although Stryker intended to promote Calstrux for use with its OP-1 products, it represented otherwise during the FDA approval process, and Calstrux ultimately received FDA approval to be marketed as "a bone void filler . . . indicated for surgically created osseous [bony] defects or osseous defects resulting from traumatic injury." *Id.* ¶ 41. FDA has never approved Calstrux for

[2] The following facts are drawn from Hricik's Complaint, the factual allegations of which this Court must accept as true in evaluating Stryker's claim of fraudulent joinder. *Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 851-52 (3d Cir. 1992).

use with BMPs such as OP-1 Implant and OP-1 Putty. In August 2004, FDA specifically advised Stryker that Calstrux would "not be approved with use of other products such as BMPs." *Id.* ¶ 39. Moreover, in December 2005, FDA declined to permit Stryker to initiate clinical trials to test the safety and efficacy of the combined use of OP-1 products and Calstrux due to safety concerns.

In connection with the company-wide launch of Calstrux in early 2005, Stryker presented Calstrux to its sales force[3] as a carrier or extender for the OP-1 products which would accelerate sales of those products. *Id.* ¶ 56. Stryker's sales force, including Cowgill and O'Dare, thereafter promoted Calstrux to surgeons, hospitals, and surgical staff, including Hricik's surgeon and the staff at the hospital where Hricik underwent surgery, as a product to be used in combination with the OP-1 products, and the vast majority of Calstrux units sold were for use with OP-1 products.

Beginning in mid-2005, Stryker began receiving reports of adverse events resulting from mixing the OP-1 products with Calstrux, including reports that in some instances the mixture had migrated from the surgical site and caused unwanted bone growth. In February 2006, Stryker received a report from a surgeon-consultant concluding that patients receiving a mixture of OP-1 products and Calstrux had higher-than-normal adverse event rates, and there was debate within the company as to whether Stryker should remove Calstrux from the market due to concerns about its safety and efficacy. Some within the company drafted a "dear doctor" letter that would have warned surgeons against using OP-1 products in combination with Calstrux until the safety and efficacy of the combined use was established. The proposed warning letter drew opposition from Stryker's National Sales Director and other sales managers and representatives, who feared

[3] According to the Complaint, Stryker had an approximately forty-person OP-1 sales force. *See* Compl. ¶ 90 (noting four Stryker sales representatives, representing "at least 10% of the entire OP-1 sales force" have pleaded guilty to felonies arising out of their illegal promotion of OP-1 and Calstrux).

the disclosure would harm sales of OP-1 products and anger surgeons who had been led to believe Calstrux was not a separate product from OP-1. Ultimately, Stryker elected not to send the "dear doctor" letter, a decision that was "celebrated" by sales and management. *See id.* ¶ 72.

Despite their knowledge that mixing OP-1 products and Calstrux was ineffective and unsafe, Stryker and its sales force continued to promote this off-label use of the products to medical providers, including Hricik's surgeon. In addition, because of restrictions on the number of units of OP-1 Putty that could be sold annually in the United States due to the limited FDA approval the product had received, Stryker provided OP-1 Implant to surgeons for use in spinal surgeries, even though OP1-Implant had only been approved for use in long-bone surgeries.

On November 27, 2007, Hricik underwent spinal surgery—an L5-S1 discectomy and bilateral Posterior Lateral Interbody Fusion—in which his surgeon used a mixture of Calstrux and OP-1 Implant.[4] Approximately a year after his surgery, Hricik began experiencing renewed and exacerbated nerve pain in his lumbar spine. Medical interventions failed to alleviate Hricik's pain, which has prevented him from working. Imaging studies of Hricik's spine performed in 2013 revealed the presence of "significant migratory unwanted bone overgrowth," which had "encased his foramen, encasing and compressing his nerves." *Id.* ¶ 104.

In March 2014, Hricik commenced this action by filing suit in the Court of Common Pleas of Philadelphia County against Stryker, Cowgill, and O'Dare. In essence, Hricik alleges Cowgill and O'Dare promoted Calstrux to his surgeon and the hospital where his surgery was performed as suitable for use with OP-1 products, and promoted the combined use of the

[4] Hricik's surgeon used Calstrux and OP-1 Implant in an off-label manner not only by mixing the two products, but also by using OP-1 Implant in a spinal surgery and in a patient with no history of prior failed spinal surgeries. OP-1 Implant had only been approved for use in long-bone surgeries. OP-1 Putty had been approved for use in certain spinal surgeries, but only in patients who had undergone a previous, unsuccessful spinal surgery.

products as safe and effective, despite knowing or having reason to know that such use, which FDA had not approved, was neither safe nor effective and could lead to unwanted bone growth and other complications, and without warning Hricik's surgeon of the inefficacy and serious risks associated with the combined use of the products. *See, e.g.*, *id.* ¶¶ 57, 98, 109, 112-13. Hricik further alleges the "Stryker Defendants," a group defined to include Cowgill and O'Dare, *id.* ¶ 14, made these misrepresentations with the intent of inducing surgeons and hospitals, including Hricik's surgeon and hospital, to use a mixture of Calstrux and OP-1 products for surgical patients, *id.* ¶ 147. He asserts that in reliance on these representations, Hricik's surgeon used a mixture of Calstrux and OP-1 Implant during his spinal surgery, which eventually resulted in unwanted bone growth in Hricik's spinal canal, causing him disabling pain and suffering. *See id.* ¶¶ 98, 104, 111, 149.[5] Based on these allegations, Hricik seeks to pursue claims for negligence, breach of express warranty, and fraud against Cowgill and O'Dare.[6]

In June 2014, Stryker removed the case to federal court on the basis of diversity jurisdiction, alleging Cowgill and O'Dare's citizenship should be disregarded for purposes of

[5] Stryker notes that while the Complaint alleges Cowgill and O'Dare trained and encouraged Hricik's surgeon to "engage in the off-label procedure of mixing Calstrux with OP-1 *Putty*," Compl. ¶ 98 (emphasis added), the OP-1 product allegedly used in Hricik's surgery was OP-1 *Implant*. This discrepancy, however, is not fatal to Hricik's claims, as the Complaint also alleges more broadly that Cowgill and O'Dare promoted Calstrux to Hricik's surgeon as suitable for use with "the OP-1 *products* . . . as a 'carrier' or 'extender,'" *id.* ¶ 57 (emphasis added), and that Hricik's surgeon used OP-1 Implant in reliance on the Stryker Defendants' representations that "the mixed use of Calstrux/OP-1 was safe and effective," *id.* ¶¶ 148-49. Moreover, the Complaint suggests spinal surgeons' use of OP-1 Implant in place of OP-1 Putty in spinal surgeries may have been unwitting. *See id.* ¶ 110 (alleging that in order to "skirt federal laws which imposed numerical limitations on the number of OP-1 Putty products . . . that could be used in a year," Stryker would "sell OP-1 Implant . . . to unwitting spinal surgeons to be used in off-label spine procedures").

[6] Although the Complaint also asserts claims against Cowgill and O'Dare for strict liability and negligent marketing, testing, and failure to withdraw, Hricik has agreed to voluntarily dismiss those claims against these Defendants.

determining whether there is complete diversity between the parties because Hricik fraudulently joined these Defendants. Stryker thereafter filed a motion to dismiss the Complaint, as did Cowgill and O'Dare, and Hricik filed the instant motion to remand. Hricik disputes that Cowgill and O'Dare were fraudulently joined and argues that because their presence as Defendants destroys complete diversity, the case must be remanded for lack of subject matter jurisdiction.[7]

DISCUSSION

The doctrine of fraudulent joinder is an exception to the requirement that when removal is predicated on diversity of citizenship, there must be complete diversity between the parties. *See In re Briscoe*, 448 F.3d 201, 215-16 (3d Cir. 2006). Under the doctrine, "[i]n a suit with named defendants who are not of diverse citizenship from the plaintiff, the diverse defendant may still remove the action if it can establish that the non-diverse defendants were 'fraudulently' named or joined solely to defeat diversity jurisdiction." *Id.* at 216. A removing defendant alleging fraudulent joinder bears a "heavy burden of persuasion." *Boyer*, 913 F.2d at 111 (citation omitted). To demonstrate a defendant was fraudulently joined, the removing party must show "there is no reasonable basis in fact or colorable ground supporting the claim against the joined defendant, or no real intention in good faith to prosecute the action against the defendant or seek a joint judgment." *Id.* (citation omitted). A claim is colorable so long as it is not "wholly insubstantial and frivolous." *Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 852 (3d Cir. 1992).

The court's inquiry with respect to a claim of fraudulent joinder is less searching than the inquiry into the validity of a complaint triggered by a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), and a court errs in evaluating a claim of fraudulent joinder under the Rule 12(b)(6) standard. *See id.* (observing "it is possible that a party is not fraudulently joined,

[7] Because the Court concludes Cowgill and O'Dare were not fraudulently joined, the Defendants' motions to dismiss are not addressed herein.

but that the claim against that party ultimately is dismissed for failure to state a claim upon which relief may be granted"). "If there is even a possibility that a state court would find that the complaint states a cause of action against any one of the resident defendants, the federal court must find that joinder was proper and remand the case to state court." *Boyer*, 913 F.2d at 111 (citation omitted); *see also Sherfey v. Johnson & Johnson*, No. 12-4162, 2014 WL 715518, at *6 (E.D. Pa. Jan. 29, 2014) (noting a finding of fraudulent joinder "is usually reserved for situations where recovery from the nondiverse defendant is a clear legal impossibility" (citation omitted)). In conducting this analysis, a court must accept as true all factual allegations of the plaintiff's complaint,[8] and must "resolve any uncertainties as to the current state of controlling substantive law in favor of the plaintiff." *Batoff*, 977 F.2d at 851-52 (citation omitted).

Stryker argues there is no reasonable basis in fact or colorable ground in law supporting any of Hricik's claims against Cowgill and O'Dare. As to Hricik's negligence claim, Stryker argues the claim is not colorable because Pennsylvania law, which the parties agree governs Hricik's claims, imposes a duty to warn on the manufacturer of a prescription medical device but imposes no duty on device sales representatives. As to Hricik's breach of express warranty and fraud claims, Stryker asserts these claims are inadequately pleaded. Stryker also maintains the learned intermediary doctrine bars Hricik's fraud claim.

Under Pennsylvania law, employees of a corporation are liable for their own torts, even if they were acting within the scope of their employment when they engaged in the tortious conduct in question. *See Pilot Air Freight Corp. v. Sandair, Inc.*, 118 F. Supp. 2d 557, 564 (E.D. Pa. 2000) (citations omitted); *Cosmas v. Bloomingdales Bros., Inc.*, 660 A.2d 83, 88-89 (Pa.

[8] Although limited consideration of evidence outside the pleadings may be permissible in some instances as part of the fraudulent joinder inquiry, *see Briscoe*, 448 F.3d at 220; *Boyer*, 913 F.2d at 112, Stryker has not asked the Court to consider any such evidence here.

Super. Ct. 1995) (observing "[a]n agent who does an act otherwise a tort is not relieved from liability by the fact that he acted at the command of the principal or on account of the principal" (citation omitted)). Pennsylvania law recognizes the participation theory, under which a corporate officer, employee, or other agent "who takes part in the commission of a tort by the corporation is personally liable therefor." *Wicks v. Milzoco Builders, Inc.*, 470 A.2d 86, 90 (Pa. 1983) (citation omitted); *see also Sannuti v. Starwood Hotels & Resorts Worldwide, Inc.*, No. 14-587, 2014 WL 1515650, at *2 (E.D. Pa. Apr. 16, 2014). To be liable under this theory, the corporate agent must have "participate[d] in the wrongful acts," a requirement the Pennsylvania courts have interpreted to permit liability for an agent's misfeasance, but not for "mere nonfeasance." *Wicks*, 470 A.2d at 90. Misfeasance consists of "the doing of something which ought not to be done, something which a reasonable man would not do, or doing it in such a manner as a man of reasonable and ordinary prudence would not do it." *Sannuti*, 2014 WL 1515650, at *2 (quoting *Brindley v. Woodland Vill. Rest., Inc.*, 652 A.2d 865, 868-70 (Pa. Super. Ct. 1995)). An employee may be liable under the participation theory for negligent as well as intentional conduct. *See, e.g.*, *Boyer*, 913 F.2d at 112 (holding employees may be liable for fraud and misrepresentation committed in the course of their employment); *Amabile v. Auto Kleen Car Wash*, 376 A.2d 247, 252 (Pa. Super. Ct. 1977) (holding employee could be liable for his own negligent conduct while acting as an agent of his employer).

Recognizing that Pennsylvania law permits a cause of action "against employees whose fraud and misrepresentations contributed to plaintiff's damages, even if these actions were taken in the course of their employment," the Third Circuit has held individual employees were not fraudulently joined in an action for fraud based in part on the employees' alleged misrepresentations. *Boyer*, 913 F.2d at 109, 112. In *Manfrey v. I-Flow Corp.*, No. 09-34, 2009

WL 636349, at *2 (E.D. Pa. Mar. 9, 2009), the court applied *Boyer* in the context of a personal injury action regarding a medical device, holding the plaintiff had stated a colorable fraud claim against an individual device sales representative based on allegations that the representative "made false statements to physicians regarding the safety of the [device] while knowing that those physicians would rely on the allegedly false representations."

Stryker argues *Manfrey* is not persuasive because the decision did not address the limiting effect of comment k to § 402A of the Restatement (Second) of Torts on the claims available in suits involving prescription drugs and medical devices, and was issued before other decisions by courts in this district finding individual drug company executives were fraudulently joined in products liability actions. The Court disagrees. Notwithstanding the Pennsylvania Supreme Court's adoption of comment k, "courts have found fraud claims concerning prescription medical devices cognizable if they contain allegations of 'overt acts,' such as affirmative misrepresentations 'that go beyond a mere failure to warn.'" *Shelley v. Ethicon, Inc.*, No. 12-6862, 2013 WL 3463505, at *3 (E.D. Pa. July 10, 2013) (quoting *James v. Stryker Corp.*, No. 10-2082, 2011 WL 292240, at *3-4 (M.D. Pa. Jan. 27, 2011)). The plaintiff in *Manfrey* alleged such affirmative misrepresentations; hence, the lack of discussion of comment k is unremarkable. Moreover, contrary to Stryker's assertion, the later decisions in which courts in this district have held plaintiffs have failed to plead colorable claims against individual drug company executives do not stand for the proposition that "a plaintiff cannot maintain a cause of action in a product liability suit against an individual defendant." Stryker's Opp'n to Pl.'s Mot. to Remand 9. Indeed, in several of the cases cited by Stryker, the courts expressly recognized the individual defendants could be liable under the participation theory for their own misfeasance, but found the plaintiffs had failed to sufficiently allege actionable misfeasance as

opposed to nonfeasance. *See Arndt v. Johnson & Johnson*, No. 12-6633, 2014 WL 882777, at *6-8 (E.D. Pa. Mar. 6, 2014) (noting the only acts of arguable misfeasance by the individual defendants—implementing phantom recalls of an over-the-counter drug and making misstatements—were not causally related to the plaintiff's injury); *see also Sherfey*, 2014 WL 715518, at *6-11; *Moore v. Johnson & Johnson*, 907 F. Supp. 2d 646, 663-65 (E.D. Pa. 2012).[9]

Stryker also argues Hricik's fraud claim is not colorable because the Complaint does not identify the specific statement that constitutes the alleged fraud and is silent as to Cowgill and O'Dare's intent in making the allegedly fraudulent statement, and because the learned intermediary doctrine precludes Hricik from establishing that he justifiably relied on any alleged misrepresentation.[10] As to the pleading defects Stryker identifies, the Complaint makes clear

[9] The remaining cases cited by Stryker in which courts in this district have found individual defendants to have been fraudulently joined are inapposite. The two cases finding fraudulent joinder in which the courts applied Pennsylvania law did not involve claims similar to the claims at issue in this case. *See Reid v. Albizem*, No. 13-4448, 2014 WL 2915883, at *5-6 (E.D. Pa. June 25, 2014) (holding a surgeon who implanted a plaintiff with a cardioverter defibrillator with wire leads was fraudulently joined in an action for breach of express warranty because the plaintiff failed to allege the warranty was set forth in a written contract, as required for a claim against a health care provider under Pennsylvania law and because a physician is not a seller within the meaning of the Pennsylvania Uniform Commercial Code); *Kallman v. Aronchick*, 981 F. Supp. 2d 372, 382 n.12 (E.D. Pa. 2013) (holding Pennsylvania law does not recognize "any duty on the part of an inventor, patent holder, or royalty owner of an FDA-approved pharmaceutical product"). The other cases cited by Stryker considered the sufficiency of claims against individual sales representatives under the law of states other than Pennsylvania. *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL No. 1203, 2004 WL 2203712, at *1-3 (E.D. Pa. Sept. 28, 2004) (applying Missouri law); *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, MDL No. 1203, 2004 U.S. Dist. LEXIS 26754, at *28-33 (E.D. Pa. June 30, 2004) (applying Texas law); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 294 F. Supp. 2d 667, 677 (E.D. Pa. July 30, 2003) (applying Georgia law); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, 220 F. Supp. 2d 414, 424-25 (E.D. Pa. Aug. 13, 2002) (applying Mississippi law).

[10] The elements of fraud under Pennsylvania law are "(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5)

that the Defendants' fraud consisted, at least in part, of misrepresenting that the mixed use of Calstrux and OP-1 products was safe and effective when, in fact, it was neither. *See* Compl. ¶¶ 145, 148, 153. The Complaint also connects Cowgill and O'Dare to these misrepresentations, and identifies Hricik's surgeon as a recipient of the misrepresentations. For example, the Complaint alleges that Cowgill and O'Dare promoted Calstrux to Hricik's surgeon and the surgical staff at the hospital where his surgery was performed as "a product to be used in combination with the OP-1 products . . . as a 'carrier' or 'extender,'" *id.* ¶ 57; that Stryker, through its sales representatives, including Cowgill and O'Dare, promoted the combined use of OP-1 products and Calstrux as safe and effective, *id.* ¶ 112(c), (h); and that the Stryker Defendants, a group that includes Cowgill and O'Dare, represented to Hricik's surgeon and hospital "that Calstrux is the 'perfect carrier for OP-1' and that it was 'safe' and 'effective' to mix Calstrux with OP-1," *id.* ¶ 138; *see also id.* ¶¶ 145, 148. Further, the Complaint alleges the Stryker Defendants made these misrepresentations "with the intent of inducing surgeons and hospitals (including [Hricik's surgeon] and the staff of [the hospital where his surgery was performed]) to use, recommend, and approve the mixed use of Calstrux and OP-1 for surgical patients." *Id.* ¶ 147. Mindful of the limited scope of the Court's inquiry with respect to allegations of fraudulent joinder, the Court concludes there is at least a possibility that a state court would find these allegations sufficient to apprise the Defendants of the representation on which Hricik's fraud claim is based and the Defendants' intent in making such representations. *See Martin v. Lancaster Battery Co.*, 606 A.2d 444, 448 (Pa. 1992) (holding a complaint satisfies the requirement of Pennsylvania Rule of Civil Procedure 1019(b) that fraud must be averred with particularity if it (1) "adequately explain[s] the nature of the claim to the opposing party so as to

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justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance." *Gibbs v. Ernst*, 647 A.2d 882, 889 (Pa. 1994).

permit the preparation of a defense" and (2) is "sufficient to convince the court that the averments are not merely subterfuge").

Nor is the Court persuaded that the learned intermediary doctrine precludes Hricik from establishing the justifiable reliance element of his fraud claim. Under the learned intermediary doctrine, when a drug or device is "available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor," who is best situated to evaluate the information and explain it to the patient in the context of his or her individual medical circumstances. *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385-86 (Pa. 1991) (quoting *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971)); *see also Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31-32 (Pa. Super. Ct. 2006) (holding the learned intermediary doctrine applies to prescription medical devices as well as drugs). Consistent with the learned intermediary doctrine, Hricik may be able to prove justifiable reliance by showing his surgeon relied on the alleged misrepresentations by Cowgill and O'Dare. Under § 310 of the Restatement (Second) of Torts,

> [a]n actor who makes a misrepresentation is subject to liability to another for physical harm which results from an act done by . . . a third person in reliance upon the truth of the representation, if the actor (a) intends his statement to induce or should realize that it is likely to induce action by . . . a third person, which involves an unreasonable risk of harm to the other, and (b) knows (i) that the statement is false, or (ii) that he has not the knowledge which he professes.

Restatement (Second) of Torts § 310 (1965). Applying § 310, the court in *Taylor v. Danek Medical, Inc.*, No. 95-7232, 1998 WL 962062, at *5 (E.D. Pa. Dec. 29, 1998), held the fact that the misrepresentations underlying a plaintiff's fraud claim "were made to the surgeon and not directly to [the plaintiff] [wa]s not a bar to her claim," so long as reliance by the surgeon was proved. *Cf. also Greenwood v. Pa. Hosp.*, No. 2250, 1999 WL 1133313, at *1-2 (Pa. Ct. Com. Pl. June 9, 1999) (holding success on negligent marketing, promotion, and misrepresentation

claims against a device manufacturer required "proof of conduct by the defendant which was directed to the physician" as a learned intermediary). Here, Hricik has sufficiently pleaded reliance under § 310, alleging the Stryker Defendants made misrepresentations regarding the suitability of Calstrux for use with OP-1 products to Hricik's surgeon, who relied on the misrepresentations in using a mixture of Calstrux and OP-1 Implant in Hricik's surgery. *See* Compl. ¶ 149. Because the surgeon is the person to whom warnings and other disclosures were required to be directed under the learned intermediary doctrine, this theory of reliance does not run afoul of the doctrine. The Court thus concludes Stryker has not shown Hricik has failed to plead a colorable fraud claim.

As to Hricik's negligence claim, Stryker focuses on Hricik's allegations with respect to the lack of adequate warnings regarding the mixed use of Calstrux and OP-1 products, asserting the only viable cause of action in a case involving a prescription drug or medical device is a claim based on the manufacturer's negligent failure to warn, and further asserting the duty to warn does not extend to individual sales representatives. Contrary to Stryker's assertion, however, Hricik's negligence claim against Cowgill and O'Dare is not premised solely on their alleged failure to warn Hricik's surgeon of the risks of mixing Calstrux and OP-1 products, but also challenges their promotion of the products to Hricik's surgeon as suitable, safe, and effective for use together, and their training and encouragement of Hricik's surgeon to use the products together, when they knew or should have known this unapproved, off-label use of the products was neither safe nor effective.[11] *See* Compl. ¶¶ 57, 98, 112-13.

[11] Failure to warn is not the only theory on which a person injured by a pharmaceutical product can recover against the manufacturer in negligence under Pennsylvania law. Indeed, in *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), the Pennsylvania Supreme Court rejected the argument that the only permissible claims against a pharmaceutical company for a lack of due care resulting in personal injury or death are claims of manufacturing defects or deficient warnings. The plaintiff

Regardless of whether individual sales representatives have a duty to warn the physicians to whom they promote medical devices about the risks associated with the devices, there is a colorable basis for a claim that sales representatives have a duty to refrain from affirmatively misrepresenting the safety and efficacy of devices for uses for which they have not been approved.[12] *See* Restatement (Second) of Torts § 311 (1965) (providing "[o]ne who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results . . . to such third persons as the actor should expect to be put in peril by the action taken"); *see also English v. Lehigh Cnty. Auth.*, 428 A.2d 1343, 1356-57 (Pa. Super. Ct. 1981) (noting liability under Restatement § 311 "is predicated on the transmission of false information" and "may arise where even if a person did not have a duty to inform, he nevertheless did inform, and in doing so, transmitted false information"). Because employees can be liable for their own misfeasance under Pennsylvania law, even when acting within the scope of their employment, and mindful that, in evaluating a claim of fraudulent joinder, "uncertainties as to the current state of controlling substantive law" are to be resolved in the plaintiff's favor, *Boyer*, 913 F.2d at 111,

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in *Lance* sought to hold the defendant pharmaceutical company liable in negligence for tendering a drug into the marketplace and continuing to market it despite having knowledge that the drug was "too harmful to be used by anyone." *Id.* at 461; *see also id.* at 450. In holding such a claim was cognizable—whether characterized as a claim for negligent design or for negligent marketing—the Supreme Court emphasized the "greater flexibility" with which it has approached "traditional, fault-based liability[,] *i.e.*, negligence," noting that while, for policy reasons, it had "declined to extend strict liability into the prescription drug arena, it . . . ha[d] not immunized drug companies from other governing aspects of Pennsylvania tort law delineating product-manufacturer duties and liabilities." *Id.* at 452-53 (emphasis omitted).

[12] Stryker argues policy considerations counsel against extending the duty to warn to individual sales representatives, who do not research or investigate medical devices and are not in a position to determine what information should be conveyed with the product, but these considerations do not support immunizing sales representatives from liability for promoting devices as safe and effective for off-label uses they know are neither.

the Court concludes Hricik's negligence claim against Cowgill and O'Dare is colorable, i.e., not wholly insubstantial and frivolous.[13]

For the reasons set forth above, the Court concludes Stryker has failed to meet its "heavy burden" to persuade the Court that there is "no reasonable basis in fact or colorable ground supporting" any of Hricik's claims against Cowgill and O'Dare. *Id.* at 111 (citation omitted). Accordingly, Hricik's motion for remand will be granted.

An appropriate order follows.

[13] Because the Court concludes Hricik's fraud and negligence claims against the individual sales representatives are colorable, the Court need not decide whether Hricik has also pleaded a colorable breach of express warranty claim.